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November 28, 2005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir/Madam:

Re: Comments on Draft Guidance for Industry on Using Electronic Means to Distribute Certain Product Information — FDA Docket No. 2005D-0385

Thomson Healthcare Inc., the publisher of *Physicians' Desk Reference*® (PDR) and a leading supplier of an array of drug, education, and clinical information tools, primarily at the point of care, to the healthcare community, strongly endorses FDA's proposed guidance concerning electronic means to distribute certain product information. As the nation's leading compendium of product information for the past six decades, *PDR* figures prominently in any discussion of the distribution and utilization of prescribing and product information. It has more extensive experience in the delivery of such information, through a variety of format and media, than any other independent organization in the United States.

The advantages of delivering information electronically are well known. Information can be sent instantly to the right individual at the right time in a cost effective manner. Receipt of such information can be automatically verified and additional contextual information can easily be linked to the primary electronic source document.

We agree, therefore, that use of information technology can significantly reduce medication errors and, when used in conjunction with decision-support systems such as our paperless labeling system, can yield major improvements in patient safety.

Thomson Healthcare has long recognized the importance of timely dissemination of certain product information to healthcare practitioners for the protection of the public health. Increasingly our methods of delivery of this information are electronic through either our website, PDR.net® (260,000 users) or our mobile application, mobilePDR® (64,000 users). Through these channels physicians can be rapidly notified of any product information changes. PDR.net can recognize individual users and push relevant information to them via an alerts function. Once a drug company's latest product information is posted on the PDR.net website, an alert can immediately follow to notify relevant physicians of the change. A link would take them directly to a PDF file for viewing or printing. Also, mobilePDR's alerts and news section delivers pertinent labeling, recall and other clinical information to users daily making both of these electronic delivery channels a highly effective and efficient means to deliver this critical drug information.

Since not all practitioners are willing to accept electronic delivery, however, we continue to distribute this type of information in print form as necessary. Over the past two decades, for example, *PDR* has worked with pharmaceutical manufacturers

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to promote the use of the *PDR Addendum,* a targeted direct mail vehicle, to communicate new and revised product labeling to prescribers and other healthcare practitioners. Studies show that the PDR addendum program is a high effective way to reach physicians: its readers open mail labeled *PDR Addendum* 96% of the time.

Under the guidance of the *Pharmaceutical Research and Manufacturers of America* (PhRMA) Paperless Labeling Task Force, Thomson Healthcare has been a thoroughly committed contributor in the effort to establish a nationwide paperless, electronic labeling system. Indeed, our paperless labeling system, PDR® *On-Demand*, provides precisely this methodology, permitting timely dissemination of communications about recalls of FDA-regulated products, important drug and product safety information, as well as easy retrieval of the latest FDA-approved product labeling (professional prescribing information). Our paperless labeling system not only permits rapid dissemination, but also provides positive confirmation that the new information has been received and retrieved. PDR *On-Demand* can provide manufacturers with the ability to disseminate important warnings to the entire pharmacy universe in less than 24 hours. In a recently completed nationwide large-scale field trial of PDR *On-Demand*, participating pharmacists viewed the PDR *On-Demand* to be a superior alternative to either paper labeling or receiving recall or safety notification via traditional mail. Dispensing staff viewed the system as superior in speed, accuracy/currency of information, ease of use, and convenience.

We strongly recommend that the FDA and drug industry work with a third party to communicate such product information in a systematic, uniform way to ensure it is promptly read by busy health professionals. Such a system would be an improvement on the current system because it would be provided by a reliable, recognized third party with credibility and experience in this area.

To reap the full benefits of a paperless labeling system, however, the agency must move forward with the regulatory actions necessary to enable such a system.. Only when the latest FDA-approved prescribing information is instantly available at every dispensing site can the full potential of technology be realized. We urge the agency to take this action.

Finally, we'd like to express our appreciation to the FDA for this opportunity to comment on the agency's initiative dealing with electronic dissemination of certain product information. We strongly support the agency's efforts to seek new ways to maximize patient benefit while minimizing risk. Lastly, we'd like to explore the many ways in which our expertise and infrastructure can be harnessed to facilitate immediate deployment of information technology to accomplish the agency and industry's patient safety initiatives, including a nationwide paperless labeling system.

Sincerely,

Mukesh Mehta, RPh
Vice President

*PDR Addenda Post Study, Feb. 2004